

PSJ9 Exh 41

CSOMP FIXES AND MODIFICATIONS REQUIRED

February 18, 2015

CSOMP Issues – Broken Functionality

1. **If a separate controlled drug order comes into CSOMP while another is pending for the same family, the system will allow the second order to go through.** This order should be pending as well (detail below)

One order for hydro held due to it being over the monthly cumulative URL. Before compliance was able to review it, a second order came in that alone did not exceed the monthly cumulative URL. This second order went right through without being held even though the first order was still pending. System is currently set that if both items are on the same order, it will pend but if both items are on separate orders, the order coming through after the first order is placed on CSOMP hold will release without going through CSOMP. We need to hold all subsequent orders of a product family while that product family is on CSOMP hold.

2. When Customer Service enters the quantity on an order, that quantity is automatically fed through CSOMP. If the amount is later modified (on the incorrect screen), that order amount also goes through CSOMP (even if the quantity would not have pending). **Need to send order through CSOMP at the completion of the order being placed not while it is still being entered.**
3. Rejection code access brought about a question as to who has access to release a “Z5” CSOMP hold. Durga was asked to pull up the screen and we learned that **448 people in the company can release a “Z5” CSOMP hold.** This needs to be limited to an extremely short list of ideally, Compliance Group personnel. May include VPDM/Ops Manager for time being but in future want to move to Compliance only.
4. Table used to total monthly usage includes three columns: (1) Usage Table = orders shipped; (2) Δ Usage = pending orders (pending to ship, not pending in CSOMP) and, (3) Order Usage = the current order. As a result of this calculation, **if an order is pending CSOMP evaluation, it will not be counted in the current monthly cumulative total.** These orders, while not frequent, do need to be considered in the calculation.

Gaps in Compliance Requirements – High Risk

5. Need to enhance CSOMP with tools to detect orders of unusual **Frequency and/or Pattern**
6. **Multiple account numbers can be assigned to one customer/DEA number.** Because the URL is assigned by account number, this may cause the customer to double or in some cases, triple the

amount of URL they are permitted. **Three account numbers = three times the URL.** This can occur if a customer has a 340B, Smartsourcing and/or standard account. While Smartsourcing accounts don't typically order controlled product, there are definitely some that do. This would require a significant change to the existing system to correct. URLs can be split across accounts (not preferred since accounts are not specifically ordering 1/3 of the URL each). Alternatively, the CSOMP system could be linked to the customer's DEA number rather than the account number.

Enhancements to cover Compliance Gaps – Medium Risk

7. Standard rejection codes in our system include "Z5" which is the CSOMP hold. In the past, others outside of the group have accidentally hit this rejection code when trying to apply a different rejection code (i.e. credit hold). This causes the order to go to CSOMP hold for no reason. **Need to gray that rejection code for all other users.**
8. **Determine way to link DBAs, sister pharmacies, name changes**
9. **Allow capability to block orders at a deeper level (by date range, by drug schedule, by product)**
10. When a CSOMP held order is released, there is a **"Reason to Remove Block" field that is all free text populated by those releasing the order. There is no consistency or control over the wording utilized.** There needs to be standard reason codes written and added in a drop down menu. The option of "Other" is still needed but should be used on a limited basis. This will allow easy interpretation and limit risk should the system be viewed by regulators. It should also allow reports to be run based on a particular reason code for trending, training or continuous improvement.

Other Regulatory Requirements

- 1) Automate ARCOS Reports
- 2) DEA Accountability Audit Report
- 3) Sugar – Modifications needed to Case Management System to increase effectiveness